EXTRAMURAL SUPPORT PROGRAM

Model Interventions to Increase Organ and Tissue Donation

FY 1999 GRANT APPLICATION GUIDANCE

May 21, 1999

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SECTION I:
INTRODUCTION

A. PROGRAM AUTHORITY AND ELIGIBILITY

This Grant Application Guidance ("Guidance") is provided to assist qualified organ procurement organizations (OPOs) and other non-profit entities eligible for funds under Section 371(a)(3) of the Public Health Service (PHS) Act, 42U.S.C. 273(a)(3), as amended, to prepare fiscal year (FY) 1999 applications for Federal funds. Funding for the Extramural Support Program - Model Interventions to Increase Organ and Tissue Donation is authorized by Public Law (P.L.) 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999. This Extramural Support Program ("Support Program") is administered by the Division of Transplantation (DoT), Office of Special Programs (OSP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS) which invites applications from consortia of institutions/organizations to participate in the FY 1999 Model Interventions to Increase Organ and Tissue Donation Program.

B. PURPOSE OF FUNDS

Funds for the Support Program are to provide direct financial assistance to Federally designated OPOs and other non-profit entities to increase organ and tissue donation. The overall goal of the Support Program is to assist eligible entities in the evaluation of, or the implementation and evaluation of, highly promising strategies and approaches that can serve as model interventions for increasing organ and tissue donation. For purposes of this program, models are defined as interventions which are: (1) effective in producing a verifiable and demonstrable impact on donation; (2) replicable; (3) transferable; and (4) feasible in practice (as defined in *Section IV-B: Review Criteria*). All projects must have rigorous methodology and evaluation components capable of ascertaining the effectiveness of the intervention(s). Projects can employ qualitative studies, quantitative research, or empiric work.

Support will be provided for projects in the following phases of model development:

(1) Phase 1 Projects: Limited or single-site pilot projects will evaluate the effectiveness of promising or previously untested interventions.

(2) Phase 2 Projects: Expanded or multi-site projects will assess the impact of interventions whose effectiveness has already been demonstrated in more limited interventions. Phase 2 projects also may include dissemination activities such as the development of training materials, the conduct of training workshops, and remote or on-site technical assistance.

(3) Phase 1 and 2 Combination Projects: A Combination Project consists of both pilot and implementation phases for a single intervention. Implementation of and funding for Phase 2

of a Combination Project, however, will be contingent upon satisfactory completion and demonstration of effectiveness in Phase 1. Approval of a Combination Project does not guarantee that the second phase will be funded. Further, the Combination Project should not be used to group distinct efforts into one application. *Complete and separate applications must be submitted for each distinct project.*

Rigorous evaluation protocols to assess the outcomes of the intervention must be included as an integral part of all proposed projects. Outcomes must be defined as the effectiveness of the intervention in improving one or more of the following performance measures: (1) organ procurement; (2) consent rates for organ donation; and, (3) declaration of intent to donate coupled with family notification of intent to become an organ donor.

Applicants have considerable flexibility in proposing interventions, including the overall focus and nature of the intervention; intervention site(s); geographic location(s); target group(s), etc. Because of the importance of improving consent, and the pronounced need for minority donors, projects focusing on consent or variations in consent by race and ethnicity are especially encouraged.

In view of the paucity of existing data-based information on the adequacy of methods to increase donation, and the critical lack of organs for transplantation, this Support Program is focused solely on interventions to increase donation. Funds will not be used for other types of projects. Examples of activities that will not be supported under this program are: biomedical and clinical research; the development and/or assessment of the efficacy of new or improved methods of donor management, organ recovery, or organ preservation; interventions to evaluate the clinical outcomes and costs of expanded donor protocols, including the use of non-heartbeating donors and living donors as a means of increasing the donor pool; fundamental research focused on new or improved evaluation tools and methodologies; fundamental research focused on the development of new behavioral theories relevant to health attitudes, practices, and decision-making; interventions inconsistent with existing Federal law or statute; and interventions to increase tissue donation alone.

C. MECHANISM OF SUPPORT

Awards made pursuant to this Guidance will be in the form of grants.

D. AVAILABILITY OF FEDERAL FUNDS

The estimated total funds available for the first year of support (direct and indirect costs) for all awards made under this Support Program in FY 1999 will be up to $5,000,000. HRSA anticipates funding approximately 15-20 projects. Although this program is provided for in HRSA's budget plans for FY 1999, awards made under this Support Program are contingent upon the availability of funds for this purpose and the receipt of a sufficient number of meritorious applications. In addition, awards to support projects beyond the first year will be contingent upon

the availability of funds, satisfactory progress in meeting project objectives, compliance with all conditions of award, and programmatic priorities of the Federal Government.

E. PERIOD OF SUPPORT

The total project period for Phase 1, Phase 2, and Combination Projects submitted in response to this Guidance may not exceed three years. Applicants are required to submit separate, detailed budgets for each proposed project year.

This Support Program is not designed to, and cannot be expected to, provide continuous support beyond the project period. In addition, at this time, HRSA has not determined whether and how this solicitation will be continued beyond the first year of funding.

F. BACKGROUND

Transplantation is the therapy of choice for many diseases leading to life-threatening end-stage organ failure. Over the past two decades, advances in surgical techniques and post-transplant therapy have improved both short- and long-term graft survival. Ongoing and future research will contribute even further to overcoming some of the remaining medical and biological obstacles. However, even if indefinite graft survival were achievable at this time, the growing number of individuals needing transplants, coupled with the inadequate number of organs available for transplantation, will remain a major barrier. The critical shortage of donor organs and the disparity between donor potential and actual donation rates have been well documented. While an estimated 8,000-15,000 deaths per year could result in organ donation, only 5,788 donors were actualized in 1998. Although this represents the largest number of donors in the United States in a single year, it falls far short of the transplant waiting list which, as of May 1999, exceeded 63,000 patients. Even with a national average recovery rate of 3.4 organs per cadaveric donor, coupled with the contribution made by living donors, less than 21,000 wait-listed Americans received transplants in 1998; more than 4,800 died waiting.

A broad spectrum of interventions to increase donation have been implemented at the national, State, and local levels by a variety of public and private organizations, ranging from large-scale national media and public education programs and statewide donor registries to community-based activities to raise awareness among various population groups. Many of these programs have yielded a considerable amount of useful descriptive information. In some instances, projects incorporating evaluation components have contributed to our knowledge about important factors associated with the donation decision-making process. However, despite this growing portfolio of activities, the effectiveness, replicability, transferability, and practicality of interventions that can serve as models have yet to be demonstrated. Further, although a great deal of information about well-validated theories and models of health behavior change has been amassed in the public health and health education literature in the past decade, this knowledge, with few exceptions, has not been applied and integrated into the design and evaluation of strategies for increasing donation.

With the aging of the baby boom generation, as well as increasing life expectancy, the current discrepancies between the need for transplantation and the supply of available organs will worsen. Faced with the current critical shortage and the likelihood of even more pronounced supply-demand disparities, organ donation is becoming an increasingly important public health issue.

In response to the urgent need for donors, Vice President Al Gore and HHS Secretary Donna E. Shalala launched the Administration's National Organ and Tissue Donation Initiative ("National Initiative") in December 1997. The goal of the National Initiative is to foster an increase in donation by increasing consent to donate, maximizing opportunities to donate, and learning more about what works to increase donation and transplantation.

Since the National Initiative's launch, HHS has fielded a number of significant projects. In April 1998, the Office of the Assistant Secretary for Planning and Evaluation, the National Institutes of Health, and the Agency for Health Care Policy and Research co-sponsored a national conference, "Increasing Donation and Transplantation: The Challenge of Evaluation," to identify methods to evaluate strategies designed to increase donation and transplantation. In June 1998, the Health Care Financing Administration (HCFA) issued a new rule to ensure that hospitals work collaboratively with OPOs in identifying potential donors and approaching families about donation. Hospitals are now required to notify OPOs of all deaths and imminent deaths and, further, to work with at least one tissue bank and one eye bank to maximize opportunities for donation. Many other activities have been implemented by the National Initiative, including the development of unique partnerships with public and private organizations focused on increasing organ and tissue donation throughout the Nation.

This Support Program represents a major Departmental component of the National Initiative and is focused exclusively on supporting projects to identify and verify successful interventions for increasing donation.

[Note: Copies of the National Initiative Partnership Kit, the Management Plan accompanying the National Initiative, the Final Report of the April 1998 conference, and a review of evaluation issues are available at www.organdonor.gov.]

SECTION II:
ELIGIBILITY REQUIREMENTS

Consortium: To promote greater collaboration throughout the country among the transplant community, other organizations with potential to encourage organ and tissue donation, and organizations with research expertise, and to ensure the breadth of expertise required for the successful design, implementation, and evaluation of promising interventions, applications must be submitted by a consortium of organizations. Applications submitted from single institutions that are not part of a consortium will *not* be accepted for review or considered for award. Each consortium member must have substantial participation in the project. While the consortium may contain any number of relevant members, it must consist at a minimum of the following two types of organizations:

a) at least one organization/institution with demonstrated expertise and experience in research and evaluation design and methods in the behavioral and social sciences; and

b) at least one organization/institution with demonstrated expertise and experience in organ donation/transplantation, including but not limited to OPOs, hospitals, and other health care organizations; community-based service organizations; public health or other government agencies.

Primary Applicant Institution: The primary applicant institution shall be legally and financially responsible and accountable to the grantor agency for the use and disposition of funds awarded to it, including any funds subcontracted to consortium members under this Support Program. This institution must demonstrate the availability of personnel and facilities capable of performing and supporting the necessary administrative functions for carrying out the role of the primary applicant institution.

According to Section 371(a)(3) of the Public Health Service Act, 426.S.C. 273(a)(3), as amended, Federally designated OPOs and other domestic, non-profit private entities are eligible to apply as the primary applicant institution. For-profit organizations and non-profit public organizations are not eligible to apply as the primary applicant institution, but may participate -- and are encouraged to participate -- as consortia members. Women, minorities, and persons with disabilities are encouraged to serve as principal investigators.

Principal Investigator The consortium shall be headed by a single principal investigator (PI) from the primary applicant institution who will be scientifically and administratively responsible for the project as a whole, including oversight of all consortium-related activities. The PI must have experience and expertise relevant to the objectives of this Support Program in one or both of the following areas: (1) the design and implementation of interventions to increase donation; and (2) the design and conduct of evaluation studies to assess the effectiveness of health interventions.

SECTION III:
INSTRUCTIONS FOR FILING THE FY 1999 APPLICATION

A. LETTER OF INTENT

Prospective applicants are asked to submit, by close of business June 7, 1999, a letter of intent that includes a descriptive title of the proposed project; the PI's name, address, e-mail address, and telephone and fax numbers; and where known, the consortium organizations. Although the letter of intent is not required, is not binding, does not commit the sender to submit an application, and does not enter into the review of subsequent applications, the information that it contains allows HRSA staff to estimate the potential review workload and to avoid conflict of interest in the review process. The letter of intent is to be sent to Glenna Wilcom at the address listed below:

Glenna Wilcom
Grants Management Officer
HRSA/OSP
5600 Fishers Lane, Room 7-27
Rockville, Maryland 20857

Tel: (301) 443-2280
Fax: (301) 594-6096
E-Mail: gwilcom@hrsa.gov

B. APPLICATION DEADLINE AND MAILING INSTRUCTIONS

1. DEADLINE

The deadline for submitting an application for the FY 1999 Extramural Support Program is July 19, 1999. To meet the deadline, applications (one complete signed original and two additional signed copies) must be ***received by*** the Grants Management Officer ***by close of business (5 p.m. EDT).***

SEND APPLICATIONS TO:

Glenna Wilcom at the address identified in *Section III-A: Letter of Intent*

Note the contents on the outside of the envelope as follows:
"Application for the Extramural Support Program - Model Interventions to Increase Organ and Tissue Donation."

2. EXTENSIONS

Extensions to the FY 1999 Support Program application deadline will not be considered.

3. FOR FURTHER INFORMATION

For further information about grant administration or fiscal issues related to the Support Program, please contact Libby Hartnett, Grants Management Specialist, at (301) 443-1913 (lhartnett@hrsa.gov). Please direct any requests for program information or technical assistance to Dr. Mary Ganikos at the postal or e-mail address listed below:

Mary L. Ganikos, Ph.D., Chief
Public and Professional Education Branch
Division of Transplantation
HRSA/OSP
5600 Fishers Lane, Room 4-81
Rockville, Maryland 20857

Tel: (301) 443-7577
Fax: (301) 594-6095
E-Mail: mganikos@hrsa.gov

SECTION IV:
REVIEW PROCESS AND CRITERIA

A. REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness and for responsiveness by HRSA staff. Applications judged to be incomplete and/or non-responsive will be returned to the applicant without review. Applications that are complete and responsive will be reviewed for scientific and technical merit by a peer review committee convened by HRSA.

The scientific and technical merit of applications will be evaluated by the peer review panel which will consist of individuals with expertise in areas such as organ donation programs and strategies; minority issues in donation needs and behavior; behavior change theories; behavioral and social research methods and evaluation strategies, etc.

The review criteria and weights to be used in the evaluation of grant applications are listed below. The peer review panel will score each application within the range of 0 to 100 points, with 100 representing the highest score.

B. REVIEW CRITERIA

1. **30 points** - Potential of the project to yield a demonstrable and verifiable increase in organ procurement, consent rates for organ donation, and/or the number of declarations of intent to donate coupled with family notification of intent to become an organ donor.

2. **25 points** - Degree of scientific rigor in the design, implementation, and evaluation of the project as evidenced by feasibility of the intervention/approach; reasonableness/appropriateness of the target populations selected; evidence from ongoing and completed work that the intervention (with or without refinement) has high potential to succeed; soundness of the measures proposed to assess effectiveness/impact; etc.

3. **20 points** - Expertise and experience of proposed project staff.

4. **15 points** - Extent to which projects are likely to be replicable, transferable, and practical as defined below.

   Replicability - effectiveness of the intervention in repeated evaluations.

   Transferability/Portability - the likelihood that the intervention can be implemented by institutions/organizations with similar competencies (e.g., human resources, funding, technology) and for target populations with similar socio-demographic profiles.

   Practicality/feasible in practice - the feasibility of implementing the intervention on a broader scale in terms of the required and available human, financial, and other resources. Evidence demonstrating the potential benefits (e.g., the likely increase in organs procured) relative to project costs also will be considered.

5. **10 points** - Adequacy of facilities, resources, and collaborative arrangements commensurate with the goals of the project.

C. ADDITIONAL REVIEW CRITERIA - FUNDING PRIORITIES

Two *funding priorities* will be employed in the assessment of applications submitted under this Support Program and additional points will be assigned to eligible applications.

1. **Five (5) points** will be assigned to applications that demonstrate high probability of having a demonstrable impact on *consent* rates for organ donation.

2. **Two (2) points** will be assigned to applications that address variations in consent by race and ethnicity. This may include an examination of differences in donation, transplantation knowledge, attitudes, and experiences among one or more racial/ethnic minority groups.

Peer reviewers will be responsible for determining the applications that qualify for these funding priorities and assigning additional points to the application's final score.

SECTION V:
INSTRUCTIONS FOR COMPLETING THE APPLICATION

A. MINIMUM REQUIREMENTS

1. Applications must include all forms and items identified in the *Application Format and Checklist*.

2. Applications must include a one-page abstract of the proposal.

3. All costs related to the implementation, or implementation and evaluation of the proposed intervention for which government funding is requested must be included in the application and fully justified. Separate budgets and budget narratives for the applicant institution and each consortium member must be included. Budgets should indicate in-kind or fiscal contributions of consortium members as well as Federal funds requested. Budgets also must include travel costs to attend the Program Coordinating Committee meetings (*Section V-F-5: Grantee Administrative Costs*). (Standard Form [SF]-424 A contained in Form PHS 5161-1 may be duplicated as necessary.)

4. Applications must include information that demonstrates compliance with the specific requirements of this Support Program as indicated earlier in *Section II: Eligibility Requirements* and *Section I-B: Purpose of Funds.*

5. Applications must include written commitment to participate in the pre-implementation as well as regular Program Coordinating Committee meetings (*Section VII-A-1: Program Coordinating Committee*).

6. *Section III: Funding Request Program Narrative* must contain the elements listed below and must not exceed 40 pages. Pagination is required in this section. Pages exceeding 40 will *not* be forwarded to the review panel.

   Required Sections:

   a. Purpose, Goals, and Objectives
   b. Background and Significance - This section should demonstrate the significance of and need for the project. Literature should be used here as supporting evidence and throughout the application as relevant.
   c. Methodology - This section should provide a thorough and complete description of the following elements. Some discussion points are provided for each element.

      Intervention - a rationale for selecting the specific intervention, particularly in terms of its potential effectiveness for increasing organ donation; where

multipronged interventions are being used, a thorough description of each facet; a review of relevant descriptive information and/or outcome data relating to feasibility and effectiveness from ongoing or completed work using the same or similar interventions, including recommended refinements/modifications; and the potential of the intervention to be effectively replicated, transported, and applied practically by institutions/organizations with similar competencies and for target populations with similar socio-demographic profiles.

Target Population(s) - a justification for the particular target population(s) selected; a description of various demographic variables within the target population(s); an indication that the consortium has the experience and expertise necessary to recruit and retain the proposed target group(s) to participate in the intervention; and plans for recruitment and retention of target group(s).

Settings - a description of and rationale for the specific setting(s) or geographic locations in which the intervention will be implemented.

Evaluation Design - a thorough description of, and rationale for, the proposed research methods including a discussion of how the proposed evaluation can be expected to produce reliable data on intervention outcomes and effectiveness; proposed performance measure(s) upon which the project will be evaluated which *must* include at least one of the following measures: organ procurement, consent rates for organ donation, and/or number of declarations of intent to donate coupled with notification of family members of intent to become an organ donor; sampling methods, number of subjects and power calculations; measurement tools, data collection, transfer and reduction; and relevance/appropriateness of the data elements to producing a verifiable and demonstrable impact on donation.

d. Timetable - a complete timetable for all phases of the proposed project.

e. Problems/Obstacles - anticipated problems that may arise and approaches for dealing with them.

f. Roles, Responsibilities, and Areas of Expertise: Consortium Members, PI, and Staff - tasks assigned and demonstration of the scientific and technical expertise required to conduct the proposed evaluation. *Table A: Consortium Membership* (page 12) should be included in this description.

g. Resources and Facilities - adequacy of the consortium's collective facilities and resources for conducting the proposed project.

TABLE A: CONSORTIUM MEMBERSHIP

ROSTER OF CONSORTIUM REPRESENTATIVES*

Project:_____

Please complete table below for all consortium representatives.

Consortium Representative: Name, Title, and Organization	Area of Expertise for Project
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

*Applicants may electronically reproduce the table and add rows or expand cells sizes as necessary.

Applicants needing assistance with preparing responses to the Table should call Mary L. Ganikos, Ph.D. at HRSA/OSP/DoT at the address and telephone number indicated in *Section III-B-3: For Further Information.*

B. GENERAL INFORMATION ON APPLICATION FORMAT

Applications for the FY 1999 Support Program must be prepared using the Public Health Service (PHS) Grant Application, PHS 5161-1, (revised 5/96) that includes SF-424 and related forms for budget and staffing requests. These forms are contained in the Application Kit mailed by the HRSA Grants Application Center, and also can be downloaded from any of the following Web sites: www.hrsa.gov; www.organdonor.gov; and www.hrsa.gov/osp/dot. In addition, as described in this Guidance, the application must include the funding request program narrative and table, (with supporting documentation in the appendices). See the checklist in *Section V-C: Application Format and Checklist* for placement of these items in the final application package.

Applicants must adhere to the following requirements. Failure to do so may result in the application being withdrawn from review.

1. **Prepare all parts of the application in English and identify the application author(s). Materials in other languages may be included only as illustrations in the appendices , but will not be evaluated by peer reviewers**.
2. **Submit all copies of application <u>UNBOUND</u>.**
3. **Use standard size black type that does not exceed 12 characters per inch.**
4. **Use 8½ by 11 inch paper that can be photocopied.**
5. **Top, bottom, left, and right margins may not be less than one inch each.**
6. **Narrative text must be 1½-spaced.**
7. **Submit Table of Contents as indicated in the Application Format and Checklist.**
8. **For Section III (Funding Request), number all pages of the application consecutively from page 1 to maximum of 40.**
9. **Do not submit double-sided copies. (Copy double-sided Federal forms on two separate pages; however, do not reproduce the second side of a Federal form if it is only instructions.)**
10. **Facsimiles and e-mail submissions will not be accepted.**
11. **Do not use photo reduction.**
12. **Do not include photos, pamphlets, or over-sized documents, unless included in appendices and copied or scanned on 8 ½ x 11 inch paper.**
13. **Requests for Funding section must be limited to a total of <u>40</u> pages, including narrative and tables. Federal forms are <u>not</u> subject to page limits. Pages in excess of 40 will not be reviewed.**
14. **Appendices must not exceed 40 pages and must be used for material that supplements the proposal, but not as a means to extend the narrative. Pages in excess of 40 will not be reviewed.**
15. **This Guidance also is available on the three Web sites listed. If you are unable to access the table from the Web sites, you may call (301) 443-7577 to request a hard copy or you may duplicate it on your computer.**

C. APPLICATION FORMAT AND CHECKLIST

The following checklist is provided to ensure that all required information is included with the application. Applicants should follow the checklist to organize and present the information required.

APPLICATION FORMAT AND CHECKLIST

- ❑ **I. Title Page**
- ❑ Table of Contents
- ❑ One (1) - page abstract of proposal
- ❑ **II. Federal Forms:**

  PHS Grant Application, Form PHS 5161-1, (revised 5/96) Requirements (This section of the application should be numbered separately from the remainder of the application, e.g., I, ii, iii.)
- ❑ SF-424: Application for Federal Assistance (Face page) (signed)
- ❑ SF-424 A: Budget Information -- Non-construction Programs
  - ❑ Section-A: Budget Summary (CFDA: 93.134)
  - ❑ Section-B: Budget Categories
  - ❑ Section-C: Non-Federal Resources (DO NOT COMPLETE)
  - ❑ Section-D: Forecasted Cash Needs (DO NOT COMPLETE)
  - ❑ Section-E: Budget Estimates for Balance of Project
- ❑ Budget Narrative/Justification
- ❑ SF-424 B: Assurances -- Non-Construction Programs (Signed)
- ❑ PHS 5161-1 Certifications -- (Debarment and Suspension, Drug-Free Workplace, Lobbying, Program Fraud) (Signed)
- ❑ Certification Regarding Environmental Tobacco Smoke (Signed)
- ❑ Checklist from PHS 5161-1 Application Kit, Page 23. The name, address, and telephone number should be provided for both the individual responsible for day-to-day program administration and the finance officer
- ❑ Intergovernmental Review under Executive Order 12372 if required by the State
- ❑ Consortium Agreements
- ❑ **III. Funding Request Program Narrative (Number from page 1 to 40.)**
  - ❑ Purpose, Goals, and Objectives
  - ❑ Background and Significance
  - ❑ Methodology (including implementation plans and tables for each project year)
  - ❑ Timetable
  - ❑ Problems/Obstacles
  - ❑ Roles, Responsibilities, and Areas of Expertise including Table A (Put vitae/resumes in appendices)
  - ❑ Resources and Facilities
- ❑ **IV. Appendices (Number from page A1 to A40.)**

D. TIPS FOR PREPARING APPLICATIONS

Applicants are urged to consider the following recommendations provided by government program officials and peer reviewers from previous grant review committees:

1. Follow the written instructions in the Guidance carefully and completely. Put required information in the appropriate section as specified in the Guidance.

2. Use the Application Format and Checklist above in *Section V-C* to organize the application, to plan and monitor application preparation, and to verify completion of all materials before submission.

3. Provide accurate and honest information. A candid account of problems and plans to address them is better than glossing over an apparent problem.

4. Certain information is requested in *Table A: Consortium Membership* (page 12) in order to standardize and condense the way information is presented and thereby facilitate the application review process. Applicants must use the format in Table A to present this information.

5. Make sure the information provided in *Table A: Consortium Membership* is consistent with the information in the narrative. Eliminate internal inconsistencies.

6. If you omit any required information or data, explain why.

7. Your application should be written for an audience not necessarily familiar with your program or the field of transplantation. Locally derived information or other data must be appropriately described in the text and the tables.

8. Where instructed in the Guidance, provide the specific documentation requested (e.g., Consortium Agreements).

9. Do not use appendices for information that is required in the body of the application.

10. Prepare the application with the reader in mind:

    a. Include the requested table of contents.
    b. Cross-reference all tables and attachments in the text of the application.
    c. Carefully proofread.
    d. Number all pages consecutively, as instructed.
    e. Provide all requested information in the sequence and format specified in this Guidance.

E. FUNDING RESTRICTIONS

1. Funds may not be used to supplant or replace current public or private research funding.

2. Funds may not be used to purchase or improve land, or to purchase, construct, or make permanent improvement to any building except for minor remodeling.

3. Funds may not be used to make payments to recipients of services, except for reimbursement of reasonable and allowable out-of-pocket expenses associated with participation in project activities.

4. Funds may not be used to support: (a) biomedical and clinical research; (b) the development and/or assessment of the efficacy of new or improved methods of donor management, organ recovery, or organ preservation; © interventions to evaluate the clinical outcomes and costs of expanded donor protocols, including the use of non-heartbeating donors and living donors as a means of increasing the donor pool; (d) fundamental research focused on new or improved evaluation tools and methodologies; (e) fundamental research focused on the development of new behavioral theories relevant to health attitudes, practices, and decision-making; (f) interventions inconsistent with existing Federal law or statute; or (g) interventions to increase tissue donation alone.

5. Allowable administrative functions/costs include:

   a. usual and recognized overhead, including indirect rates for all consortium members which have a Federally approved indirect cost rate; and

   b. management and oversight of specific programs funded under the Support Program.

6. Unobligated funds at the end of the budget period are restricted and remain in the grant account for future HRSA disposition. These funds may be approved for carryover to the next budget period. Unobligated funds are those reported on the annual Financial Status Report which is required to be submitted to HRSA/OSP 90 days after the end of the budget period *(*See *Section VII-C: Activities and Requirements*.) These funds may be used to adjust the amount of the award for the next fiscal year. Unobligated funds are defined as:

   a. Funds budgeted for administration, program support, research, or that have been contracted, that are unexpended at the end of the budget period in which the funds were awarded; and

   b. Funds that are not obligated at the end of the budget period in which the funds were awarded.

7. Funds are to be used consistent with future program policies developed by DoT.

F. SUPPLEMENTAL INSTRUCTIONS FOR COMPLETING STANDARD FORM-424

The following information supplements the instructions that are included in PHS Form 5161-1 for completing the SF-424 and related forms.

1. SF-424 FORM (FACE PAGE)

   a. Item 5: Enter the legal name and address of the applicant organization as recognized by the Internal Revenue Service.

   b. Item 6: Enter the 9-digit Employer Identification Number assigned by the Internal Revenue Service. For organizations that receive, or have received, funding from the Department of Health and Human Services, enter the 12-digit modified Employer Identification Number on page 23 (Checklist) of the Form PHS 5161-1.

   c. Item 10: Enter 93.134.

   d. Item 11: Identify the Phase(s) (Phase 1, Phase 2, or Phase 1 and 2 Combination) covered by this application.

   e. Item 13: Include the period of time covering the proposed project not to exceed 3 years. Project periods will begin 10/1/99.

   f. Item 14a.: Identify the specific congressional district in which the applicant organization is located. Only one congressional district may be included in 14a.
   Item 14b.: Identify all congressional districts affected by the program or project.

   g. Item 15a.: Identify the amount of Federal assistance requested for the first 12-month budget period beginning 10/1/99.

   h. Executive Order 12372 establishes a system for State and local government review of proposed Federal assistance applications. Applicants should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective application and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current list of SPOCs for participating States is included in the application kit and on the four following web sites:

www.hrsa.gov; www.organdonor.gov; www.hrsa.gov/osp/dot; and www.dhhs.gov/progorg/grantsnet/laws-reg/spoc399.htm. The SPOC has 60 days after the application deadline date to submit recommendations to HRSA/OSP for competing applications.

i. Item 18: The application must be signed by an authorizing official of the applicant organization.

2. SF-424A, BUDGET INFORMATION - NON-CONSTRUCTION PROGRAMS

a. Section A: Complete for the first 12-month period of support requested beginning 10/1/99.

b. Section B: Use each column to present the budget for each consortium member. Use as many forms as necessary. On a separate form show the budget for the applicant organization and the total for the entire project. Use the instructions below for preparing the budget narrative justification. *A separate budget narrative justification must be provided for each consortium member.*

Line item 6(f) requests a total budget of all contract arrangements. A budget and narrative justification for all activities contracted out also must be submitted as part of the budget.

Allowable costs are determined using the cost principles prescribed for grant recipients by the Office of Management and Budget (OMB) and can be found in OMB Circulars A-87, A-21, and A-122 (www.whitehouse.gov/WH/EOP/OMB/html/circular-top.html). Information also may be obtained from the PHS Grants Policy Statement (www.nih.gov/grants/policy/gps/).

Indirect charges may be included only if the organization has a Federally approved indirect cost rate. A copy of the negotiated indirect rate agreement must be included for each consortium member. All other costs must be identified as direct costs. Usual and recognized overhead may be included but must be identified as direct costs.

c. Sections C and D: Do not complete.

d. Section E: Complete for all remaining fiscal years of project period not to exceed FY 2002. (Use October 1 as the beginning of each fiscal year.)

3. BUDGET AND BUDGET NARRATIVE JUSTIFICATION PREPARATION

In addition to completing SF-424A, a line-item categorical budget and supporting budget narrative must be submitted for the entire project, including detailed budgets for each consortium member participating in the project, and for each contract and subcontract to be used with funds awarded to the applicant institution. Separate budgets must be submitted for each project year. Budgets must be prepared using the applicable Cost Principles found at: www.whitehouse.gov/WH/EOP/OMB/html/circular-top.htm.

The budget narrative is the descriptive information used to explain and justify the amounts budgeted. ALL costs in the budget, including those listed in "other" must be described and justified.

Personnel: List all personnel whose salaries are to be paid in whole or in part with project funds. For each position, provide the job title, the last name of the employee, a brief description of the duties and responsibilities of the employee as they relate to the funded activities, annual salary, percentage of time to be devoted to and paid for by this grant, and the amount to be charged to the grant.

If a position is vacant, indicate such and provide an estimated date when the position will be filled.

Fringe Benefits: Provide the aggregate amount of fringe benefit. It is not necessary to provide the calculations for arriving at the amount of fringe benefits.

Travel: All travel must directly benefit and be specific to the supported work. List all travel anticipated to occur during the budget period; be specific about who will travel where and when and why the travel is necessary.

Equipment: List only the equipment that is being purchased with grant funds. Be specific in describing what equipment is being purchased, who will use the equipment and why is it necessary to purchase the equipment. A purchase versus lease analysis should be done for large dollar items. Cost sharing must be applied when equipment will be used for other than project-related activities.

Supplies: A general description of the type of items classified as supplies must be provided. Computer software should be included in this category.

Contractual: Include in this category all funds that are to be contracted out.

Other: This category should include other items associated with the evaluation, or implementation and evaluation, of the proposed intervention, such as measurement tools, data analysis, telephone, postage, advertising, training, brochures, or other materials/activities. A cost and descriptive justification for

each item listed must be provided. Be specific in describing each item in terms of what it is and why it is necessary.

Indirect Costs: Allowable only with a Federally approved indirect cost rate. Include a copy of the negotiated indirect cost rate agreement to support the amount included in the budget.

4. FORM PHS 5161-1 - CHECKLIST - PAGE 23

a. Part A and B: Complete. For first-time applicants, the assurance of compliance for civil rights, handicapped, sex discrimination, and age discrimination (Form HHS 690) can be downloaded from the web site www.hhs.gov/progorg/ocr.

b. Part C: Administrative Official refers to the official responsible for the fiscal integrity of the grant (business office). For applicants who have received HHS funding, provide the 12-digit Employer Identification Number.

Principle investigator refers to the official responsible for the accomplishing project activities and program reporting. The PI must be an employee of the applicant organization. Do *not* provide the Social Security Number of the PI.

c. Section D: Complete

5. GRANTEE ADMINISTRATIVE COSTS

Funds to be used by the project for routine project administration and monitoring activities shall include the receipt and disbursal of program funds, the development and establishment of reimbursement and accounting systems, the preparation of routine programmatic and financial reports, and compliance with awards conditions and audit requirements and all activities associated with the award procedures, including the development of requests for proposals, contract proposal review activities, negotiation and awarding of contracts, development and implementation of grievance procedures, monitoring of contracts through telephone consultation, written documentation or on-site visits, reporting on contracts, and funding reallocation activities.

A budget narrative must be included which provides a line-item breakdown of the budget, detailing the amount of funds budgeted for each item. **Applicants are instructed to include in their administrative budgets travel funds for the PI and one senior project staff member to the Washington, D.C. area for a maximum of seven one and one-half day Program Coordinating Committee meetings (one pre-implementation meeting and two additional meetings for the first year of the**

proposed project and two meetings per year thereafter for the remainder of the proposed project period). If such meetings are not held, the grantee will be encouraged to re-budget these funds as necessary. Administrative activities may not be included under other budgetary categories.

Administrative support includes the *reasonable and necessary* activities listed below.

a. Staff support (e.g., clerical and professional expenses required by the project).

b. Costs incurred by consortium members as a result of their participation in the project. Consortium support activities should be listed separately and a budget justification should address each activity.

6. ORGANIZATIONAL CHANGES

A change in the PI, or in any key personnel identified on the Notice of Grant Award must have the prior written approval of the HRSA Grants Management Specialist in consultation with Program Officials at DoT.

SECTION VI:
GRANT AWARDS

A. ADDITIONAL AWARD CONSIDERATIONS

HRSA reserves the option to achieve a balance among funded projects with respect to various parameters, e.g., target population; geography; balance of Phase 1, Phase 2, and Combination Projects; and mix of interventions.

B. EARLIEST AWARD DATE

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All awards will be made prior to or by September 30, 1999.

The PI will receive a Notice of Grant Award in writing specifying the amount of Federal funds available under the Support Program for FY 1999. To assure timely notification, PIs should forward any address or telephone changes as soon as possible, whenever such changes occur, to Grants Management Officer, HRSA/OSP, Room 7-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

SECTION VII:
ACTIVITIES AND REQUIREMENTS

A. SPECIAL REQUIREMENTS

1. PROGRAM COORDINATING COMMITTEE

In order to ensure coordination/collaboration among grantees, maximize effectiveness and efficiency, and allow flexibility in the face of rapid changes in the field, all funded projects will be reviewed at a pre-implementation meeting, and regularly thereafter, by a Program Coordinating Committee. The Committee will consist of: the PI and one senior investigator from each funded project; additional experts in organ donation, research design, and program evaluation; and others as may be identified by the government. HRSA staff and other Federal representatives will atend these meetings and provide technical assistance as needed. One pre-implementation meeting and two additional meetings will be scheduled for the first year. Two meetings will be scheduled for each year of the remainder of the project period. In addition, project review conference calls will be held three times per year.

The purpose of the pre-implementation and periodic meetings is to discuss the critical components of each project; assess progress; identify problem areas and potential solutions; and develop strategies for achieving maximum efficacy of each project. The Committee will review and provide suggestions on issues such as the intervention, design, methodology, budget, and parameters of each project; appropriate outcome and performance measures; definitions of terms and consistency in defining terms among the grantees; the use of

qualitative measurements to improve the usefulness of data collection and analysis for individual projects and across all projects; and modifications/refinements as may be appropriate to ensure continued feasibility and usefulness. Suggested budget revisions commensurate with project revisions must be submitted to the Federal Government for consideration.

2. DATA COORDINATION AND MANAGEMENT

Each grantee will be responsible for the collection, entry, quality control, and analysis of all project data. Grantees will provide interim data and plans for proposed analyses to the Program Coordinating Committee as requested. Patient privacy and confidentiality must be protected in accordance with the Privacy Act.

3. PUBLICATION AND PRESENTATION OF PROJECT FINDINGS

Publication of major findings is encouraged. *All* publications and oral presentations of work performed under, and data resulting from this grant must contain appropriate acknowledgment of HRSA support and a disclaimer as follows: "This publication/presentation was supported by Grant #____ from the Health Resources and Services Administration's Division of Transplantation (HRSA/DoT), U.S. Department of Health and Human Services. The contents of this publication/presentation are solely the responsibility of the authors and do not necessarily represent the views of HRSA/DoT." In addition, HRSA must be notified in advance of all publications and presentations to enable coordination of announcements about the oral or written presentation of information resulting from the project funded under the Support Program.

B. POST-AWARD MONITORING

In addition to the review functions of the Program Coordinating Committee discussed above in *Section VII-A: Special Requirements*, DoT program officials will monitor through required progress reports and conference calls overall consortium responsiveness and effectiveness in implementing their projects and suggestions of the Program Coordinating Committee. Progress related to identified deficiencies will be monitored and a continued lack of progress could result in special conditions on the FY 2000 Notice of Grant Award, if applicable. Subsequently, any special conditions issued for FY 2000 will be subject to an internal review with the Fiscal Year 2001 Notice of Grant Award, if applicable.

C. PROGRAM PROGRESS REPORT

Grantees must report to the HRSA/OSP Grants Management Office regarding the progress of implementing model interventions and funded program activities under this Support Program in accordance with applicable provisions of the general regulations (45 CFR Part 92, Sub-part C, Monitoring and Reporting of Program Performance), and in accordance with the specifications of the Support Program. Guidance in preparing FY 1999 program progress reports will be provided by DoT.

Grantees are responsible for ensuring that the consortium organizations they fund for the project provide sufficient information so that the applicant institution can satisfactorily fulfill HRSA's reporting requirements.

D. OTHER REQUIREMENT REPORTS

An annual Financial Status Report is required to be submitted to HRSA/OSP Grants Management Office, 90 days after the end of the budget period. In addition to program progress reporting requirements, grantees may be expected to provide information for to other HRSA or Departmental performance measurement activities.